**PATENT** Docket No. 9222.16632-CIP CON

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Box Patent Application Assistant Commissioner for Patents** Washington, D.C. 20231



# NEW APPLICATION TRANSMITTAL Under 37 CFR § 1.53(b)

Transmitted herewith for filing is the patent application of

Inventor(s):

David Utley and Stuart D. Edwards

WARNING: 37 C.F.R. § 1.41(a)(1) points out:

'(a) A patent is applied for in the name or names of the actual inventor or inventors.

(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by § 1.63, except as provided for in § 1.53(d)(4) and § 1.63(c). If an oath or declaration as prescribed by § 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to § 1. 53(b), unless a petition under this paragraph accompanied by the fee set forth in § 1.17(i) is filed supplying or changing the name or names of the inventor or inventors.

For (title):

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Systems and Methods for Monitoring and Controlling Use of Medical Devices

#### CERTIFICATION UNDER 37 C.F.R. 1.10\*

(Express Mail label number is mandatory.) Express Mail certification is optional.)

I hereby certify that this New Application Transmittal and the documents referred to as attached therein are being deposited with the United States Postal Service on this date 10 October 2001 \_, in an envelope as 'Express Mail Post Office to Addressee' mailing Label Number addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Judith Biebel

or print name of person mailing paper)

Signatu of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing

or transmission for this correspondence.

WARNING: Each paper or fee filed by "Express Mail" must have the number of the Express Mail mailing label placed thereon prior to mailing.

37 CFR 1.10(b).

"Since the filing of correspondence under  $\S$  1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition. 'Notice of Oct. 24, 1996,

60 Fed. Reg. 56,439, at 56,442.

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|-----|----------------|------|--------|-------|
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| I + | IVDC           | UI A | DDIICE |       |

This new application is for a(n)

|         |     |     | (check one applicable item below)   |
|---------|-----|-----|---|
|         | [   | ]   | Original (nonprovisional)   |
|         | [   | ]   | Design  |
|         | [   | ]   | Plant   |
| WARNING | G:  |     | <b>not</b> use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. $371(c)(4)$ , unless the ernational Application is being filed as a divisional, continuation or continuation-in-part application.        |
| WARNING | G:  | Do  | not use this transmittal for the filing of a provisional application.   |
| NOTE:   |     | BE  | one of the following 3 items apply then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE<br>NEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF<br>IIS CONTINUATION APPLICATION. |
|         | [   | ]   | Divisional.   |
|         | [ : | x ] | Continuation.   |

#### 2. Benefit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)

Continuation-in-part (C-I-P).

NOTE:

A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S. C. 112. Each prior application must also be:

- An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of (i) America; or
- (ii) Complete as set forth in § 1.51(b); or
- (iii)
- Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) (iv) within the time period set forth in § 1.53(f). 37 C.F.R. § 1.78(a)(1).

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent

case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S.

APPLICATION(S) CLAIMED.

WARNING:

If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

WARNING: Whe

When the last day of pendency of a provisional application falls on a Saturday, Sunday, or Federal holiday within the District of Columbia, any nonprovisional application claiming benefit of the provisional application must be filed prior to the Saturday, Sunday, or Federal holiday within the District of Columbia. See 37 C.F.R. § 1.78(a)(3).

[x] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.

#### 3. Papers Enclosed

| A. Required for filing da | ite under 37 C.F.R. | 1.53(b) (Regular) | or 37 C.F.R. 8 | § 1.153 Design) Application |
|---------------------------|---------------------|-------------------|----------------|-----------------------------|
|                           |                     |                   |                |                             |

| _20 | Pages of  | specification |
|-----|-----------|---------------|
| _05 | Pages of  | claims        |
| 01  | Abstract  |               |
| _08 | Sheets of | f drawing     |
|     | [ x ]     | formal        |
|     | [ ]       | informal      |

B. Other documents enclosed:

WARNING:

DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to § 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 CFR 1.84, see Notice of March 9, 1988 (1990 O.G. 57-62).

NOTE:

"Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawing a minimum distance of 1.5 cm. (518 inch) down from the top of the page . . . "37 C.F.R. 1.84(c)).

(complete the following, if applicable)

| [ ] | The enclosed drawing(s) are photograph(s), and there is also attached a "PETITION TO ACCEPT |
|-----|---|
|     | PHOTOGRAPH(S) AS DRAWING(S)." 37 C.F.R. 1.84(b).  |

# 4. Additional papers enclosed

| [ x ] | Preliminary Amendment  |
|-------|--|
| [ x ] | Information Disclosure Statement (37 C.F.R. 1,98)  |
| [ x ] | Form PTO-1449 (PTO/SB/08A and 08B)   |
| [ ]   | Citations  |
| []    | Declaration of Biological Deposit  |
| [ ]   | Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for |
|       | biotechnology invention containing nucleotide and/or amino acid sequence.                        |
| [ ]   | Authorization of Attorney(s) to Accept and Follow Instructions from Representative               |
| [ ]   | Special Comments   |
| [ ]   | Other  |
|       |  |

5. Declaration roath

11

| NOTE:   | A newly executed declaration is not required in a continuation or divisional application provided that the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under § 1.47, then a copy of that declaration must be filed accompanied by a copy of the decision granting § 1.47 status or if a nonsigning person under § 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. ff 1.63(cO. |
|---------|--|
|         | <ul> <li>[ ] Enclosed</li> <li>[ ] newly executed</li> <li>[ ] copy from parent application identified above</li> <li>Executed by (check all applicable boxes)</li> <li>[ ] inventor(s).</li> <li>[ ] legal representative of inventor(s).</li> <li>37 CFR 1.42 or 1.43.</li> <li>[ ] joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.</li> <li>[ ] This is the petition required by 37 CFR 1.47 and the statement required by 37 CFR 1.47 is also attached. See Item 13 below for fee.</li> </ul>  |
|         | [x] Not Enclosed.  |
| NOTE:   | Where the filing is a completion in the U.S. of an International Application or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.   |
|         | <ul> <li>[x] Application is made by a person authorized under 37 C.F.R. 1.41(c) on behalf of all the above named inventor(s).</li> <li>(The declaration or oath, along with the surcharge required by 37 CFR 1. 16(e) can be filed subsequently).</li> </ul>   |
| NOTE:   | It is important that all the correct inventor(s) are named for filing under 37 CFR 1.41(c) and 1.53(b).  |
|         | [ ] Showing that the filing is authorized. (not required unless called into question. 37 CFR 1.41(d))  |
| 6.      | Inventorship Statement   |
| WARNING | G: If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.   |
|         | The inventorship for all the claims in this application are:   |
|         | [x] The same.  |
|         | or   |
|         | [ ] Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made  |
|         | [ ] is submitted. [ ] will be submitted.   |

NOTE:

APPLICATION(S) CLAIMED.

7.

Language

| NOTE:  |  | processing fee of \$130.00 required by 37           | e other than English. An English translation of the non-<br>CFR 1.17(k) is required to be filed with the application, |
|--------|--|---|---|
|        | [x] English [] Non-English [] The attached tran                              | slation includes a statement that th                | ne translation is accurate. 37 C.F.R. 1.52(d).  |
| 8.     | Assignment   |   |   |
|        | [ ] is attached. A ACCOMPANYIN [ ] will follow.                              |   | EET FOR ASSIGNMENT (DOCUMENT) ON or [ ] FORM PTO 1595 is also attached.   |
| NOTE:  | "If an assignment is submitted with a<br>Notice of May 4, 1990 (1114 O.G. 77 | new application, send two separate letter<br>7-78). | rs - one for the application and one for the assignment"  |
| WARNIN | NG: A newly executed "CERTIFICAT<br>assignee. Notice of April 30, 199        |   | when a continuation-in-part application is filed by an  |
| 9.     | CERTIFIED COPY Certified copy(ies) of applicat                               | tion(s)   |   |
|        | Country  | Appln. No.  | Filed   |
|        | Country  | Appln. No.  | Filed   |
|        | Country  | Appln. No.  | Filed   |
| -      | Country  | Appln. No.  | Filed   |
|        | from which priority is claimed   | 1   |   |
|        | [ ] is (are) attached.   |   |   |
|        | [ ] will follow.   |   |   |
| NOTE:  | The foreign application forming the l  | basis for the clam for priority must be refe        | erred to in the oath or declaration. 37 CFR 1.55(a) and   |

This item is for any foreign priority for which the application being filed directly relates. If any parent U.S. application or International Application from which this application claims benefit under 35 U.S.C. 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S.

### **10.** Fee Calculation (37 C.F.R. 1.16)

#### A. [x] Regular application

|   | C           | CLAIMS AS | S FILED      |            |   |
|---|-------------|-----------|--------------|------------|---|
|   | Number File | ed        | Number Extra | Rate       | Basic Fee<br>37 CFR 1.16(a)<br>\$740.00 |
| Total Claims 37 CFR 1.16(c)               | 22          | -20 =     | 2            | x \$ 18.00 | 36                                      |
| Independent Claims (37 CFR 1.16(b)        | 3           | - 3 =     | 3            | x \$ 84.00 | 0                                       |
| Multiple Dependent claim(s) if any (37 CI | FR 1.16(d)) |           |              | + \$280.00 | 0                                       |

| l | <br>Amendment cancelling extra claims enclosed.      |
|---|--|
|   | Amendment deleting multiple-dependencies enclosed.   |
| ĺ | Fee for extra claims is not being paid at this time. |

NOTE: If the fees for extra claims are not paid on filing they must be paid or the claims cancelled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 CFR 1. 16(d).

|      |   | Filing Fee Calculation      | 740.00 |
|------|---|-----------------------------|--------|
| B.   | [ ] Design application<br>(\$320.00 - 37 CFR 1.16(f)) | Filing Fee Calculation      |        |
| C. [ | ] Plant application<br>(\$490.00 - 37 CFR 1.16(g)     | )<br>Filing Fee Calculation |        |

# 11. Small Entity Statement

| [x] | The applican | nt is a Small Entity as defined by | 37 CFR 1.9 and 1.27 and is entitled to small entity status. |
|-----|--------------|------------------------------------|---|
|     | [ x ]        | Small Entity Filing Fee:           | \$370.00  |

WARNING: "Status as a small entity must be specifically established in each application or patent in which the status is available and desired. Status as a small entity in one application or patent does not affect any other application or patent, including applications or patents which are directly or indirectly dependent upon the application or patent in which the status has been established. The refiling of an application under § 1.53 as a continuation, division, or continuation-in-part (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application requires new determination as to continued entitlement to small entity status for the continuing or reissue application. A nonprovisional application claiming benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) of a prior application, or a reissue application may rely on a statement filed in the prior application or in the patent if the nonprovisional application or the reissue application includes a reference to the statement in the prior application or in the patent or includes a copy of the statement in the prior application or in the patent and status as a small entity is still proper and desired. The payment of the small entity basic statutory filing fee will be treated as such a reference for purposes of this section." 37 C.F.R. § 1.28(a)(2).

NOTE: Any excess of the full fee paid will be refunded if small entity status is established and a refund request are filed within 2 months of the date of timely payment of a full fee. The two-month period is not extendable under § 1.136, 37 CFR 1.28(a).

| 2.    | Request for International-Type Search (37 C.F.R. 1.104(d))  |  |  |  |  |  |  |
|-------|---|--|--|--|--|--|--|
|       | (complete, if applicable)   |  |  |  |  |  |  |
|       | [ ] Please prepare an international-type search report for this application at the time when national examination on the merits takes place.  |  |  |  |  |  |  |
| 13.   | Fee Payment Being Made at This Time   |  |  |  |  |  |  |
|       | [x] Not Enclosed  |  |  |  |  |  |  |
|       | [x] No filing fee is to be paid at this time.  (This and the surcharge required by 37 C.F.R. 1. 16(e) can be paid subsequently.)  |  |  |  |  |  |  |
|       | [ ] Enclosed  |  |  |  |  |  |  |
|       | [ ] Filing fee  |  |  |  |  |  |  |
|       | [ ] Recording assignment     (\$40.00; 37 C.F.R. 1.21(h))     (See attached 'COVER SHEET FOR     ASSIGNMENT ACCOMPANYING NEW     APPLICATION.)  |  |  |  |  |  |  |
|       | [ ] Petition fee for filing by other than all the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached  (\$130.00; 37 C.F.R. 1.47 and 1.17(i)  |  |  |  |  |  |  |
|       | [ ] For processing an application with a specification in a non-English language (\$130.00; 37 C.F.R. 1.52(d) and 1.17(k))  |  |  |  |  |  |  |
|       | [ ] Processing and retention fee<br>(\$130.00; 37 C.F.R. 1.53(d) and 1.21(l))   |  |  |  |  |  |  |
|       | [ ] Fee for international-type search report (\$40.00; 37 C.F.R. 1.21(e))   |  |  |  |  |  |  |
| NOTE: | 37 CFR 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 CFR 1.53(a and this, as well as the changes to 37 CFR 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of § 1.21(l) must be paid, within 1 year from notification under § 53(f). |  |  |  |  |  |  |
|       | Total fees enclosed - 0 -   |  |  |  |  |  |  |

| 14.              | Method of Payment f Fees  |  |  |  |  |  |  |  |
|------------------|---|--|--|--|--|--|--|--|
|                  | [ ] Checl   | c in the amount of \$  |  |  |  |  |  |  |
|                  |   | ge Account No in the amount of  blicate of this transmittal is attached.   |  |  |  |  |  |  |
| NOTE:            | Fees should be i  | temized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).   |  |  |  |  |  |  |
| 15.              | Authorizatio  | n to Charge Additional Fees  |  |  |  |  |  |  |
| WARNI.<br>WARNI. | NG If no fees are<br>NG Accurately c<br>authorized.   | e to be paid on filing, the following items should <u>not</u> be completed.<br>count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are  |  |  |  |  |  |  |
|                  | the en  | commissioner is hereby authorized to charge the following additional fees by this paper and during stire pendency of this application to Account No  |  |  |  |  |  |  |
| NOTE:            | claims cancelled<br>CFR 1.16(d)), It<br>after final action<br>[ ] 3<br>tl                             | nal fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments of C.F.R. 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)  7 C.F.R. §§ 1.17(a)(I-5) (extension fees pursuant to § 1.136(a)).  7 C.F.R. 1.17 (application processing fees)  |  |  |  |  |  |  |
| NOTE:            | for an extension<br>appropriate leng<br>be treated as a co<br>time under this p<br>petition for an ex | may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the thof time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of aragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive tension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely E.F.R. 1. 136(a)(3). |  |  |  |  |  |  |
|                  | [ ]   | 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311(b))   |  |  |  |  |  |  |

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application.... prior to paying, or at the time of paying, ... issue fee." From the wording of 37 CFR 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

| NOTE                       | " Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payobe notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account 37 C.F.R. § 1.26(a). |                   |                                  |  |  |  |  |  |
|----------------------------|---|-------------------|----------------------------------|--|--|--|--|--|
|                            | [ ]   | Credit Account No |                                  |  |  |  |  |  |
|                            | [ ]   | Refund            | was                              |  |  |  |  |  |
|                            |   |                   | SIGNATURE OF PRACTYTIONER        |  |  |  |  |  |
| Reg. 1                     | No. 29,   | 243               | Daniel D. Ryan                   |  |  |  |  |  |
|                            |   |                   | (type or print name of attorney) |  |  |  |  |  |
| Tel. No.: (262) 783 - 1300 |   |                   | RYAN KROMHOLZ & MANION, S.C.     |  |  |  |  |  |
|                            |   |                   | (P.O. Address)                   |  |  |  |  |  |
|                            |   |                   | Post Office Box 26618            |  |  |  |  |  |
|                            |   |                   |                                  |  |  |  |  |  |
|                            |   |                   | MILWAUKEE, WISCONSIN 53226       |  |  |  |  |  |

Instructions as to Overpayment

16.

[ ]

| [x] | Incorporation by reference of added pages  |  |  |  |  |  |  |
|-----|--|--|--|--|--|--|--|
|     | (check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED) |  |  |  |  |  |  |
|     | [ x ]  | Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. |  |  |  |  |  |

| [X]          | Application(s) Claimed   |
|--------------|--|
|              | Number of pages added 4  |
| []           | Plus Added Pages for Papers Referred to in Item 4 Above  |
|              | Number of pages added  |
| []           | Plus added pages deleting names of inventor(s) named in prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application. |
|              | Number of pages added  |
| []           | "Assignment Cover Letter Accompanying New Application"   |
|              | Number of pages added  |
|              |  |
| (if no furth | t Where No Further Pages Added ner pages form a part of this Transmittal, then end this Transmittal with this page and following item)                           |
| []           | This transmittal ends with this page.  |

**PATENT** 

# ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED

NOTE: "In order for an application to claim the benefit of a prior filed copending national application, the prior application must name as an inventor at least one inventor named in the later filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112." 37 CFR 1.78(a).

NOTE: "IN ADDITION THE PRIOR APPLICATION MUST BE (1) COMPLETE AS SET FORTH IN S 1.51, OR (2) ENTITLED TO A FILING DATE AS SET FORTH IN S 1.53(B) AND INCLUDE THE BASIC FILING FEE SET FORTH IN S 1.16; OR (3) ENTITLED TO A FILING DATE AS SET FORTH IN S 1.53(B) AND HAVE PAID THEREIN THE PROCESSING AND RETENTION FEE SET FORTH IN S 1.21(L) WITHIN THE TIME PERIOD SET FORTH IN S 1.53(D)."37 CFR 1.78(A).

# 17. Relate Back-35 U.S.C. 120

IOTE: "ANY APPLICATION CLAIMING THE BENEFIT OF A PRIOR FILED COPENDING NATIONAL OR INTERNATIONAL APPLICATION MUST CONTAIN OR BE AMENDED TO CONTAIN IN THE FIRST SENTENCE OF THE SPECIFICATION FOLLOWING THE TITLE A REFERENCE TO SUCH PRIOR APPLICATION IDENTIFYING IT BY SERIAL NUMBER AND FILING DATE OR INTERNATIONAL APPLICATION NUMBER AND INTERNATIONAL FILING DATE AND INDICATING THE RELATIONSHIP OF THE APPLICATIONS." 37 CFR 1.78(A). SEE ALSO THE NOTICE OF APRIL 28, 1987 (1079 O.G. 32 TO 46).

[x] The specification includes the following recitation:

#### Related Application:

This application is a continuation of co-pending U.S. Patent Application Serial Number 09/495,390, filed January 31, 2000, and entitled "Systems and Methods for Monitoring and Controlling Use of Medical Devices," which is a continuation-in-part of co-pending United States Patent Application Serial Number 09/026,296, filed February 19, 1998, and entitled "Method for Treating a Sphincter" (now U.S. Patent No. 6,009,877) and a continuation-in-part of co-pending provisional United States Patent Application Serial Number 60/152,749, filed September 8, 1999 and entitled "Systems and Methods for Monitoring and Controlling Use of Medical Devices."

NOTE: THE PROPER REFERENCE TO A PRIOR FILED PCT APPLICATION WHICH ENTERED THE U.S. NATIONAL PHASE IS THE U.S. SERIAL NUMBER AND THE FILING DATE OF THE PCT APPLICATION WHICH DESIGNATED THE U.S.

NOTE: (1) WHERE THE APPLICATION BEING TRANSMITTED ADDS SUBJECT MATTER TO THE INTERNATIONAL APPLICATION THEN THE FILING CAN BE AS A CONTINUATION-IN-PART OR (2) IT IS DESIRED TO DO SO FOR OTHER REASONS, E.G. WHERE NO DECLARATION IS AVAILABLE, NO ENGLISH TRANSLATION IS AVAILABLE OR NO FEE IS TO BE PAID ON FILING THEN THE FILING CAN BE AS A CONTINUATION. IN THESE CASES THE INTERNATIONAL APPLICATION DESIGNATING THE U.S. IS TREATED AS THE PARENT CASE IN THE U.S. AND IS AN ALTERNATIVE TO THE COMPLETION OF THE INTERNATIONAL APPLICATION UNDER 35 U.S.C. 371(C)(4) WHICH MUST MEET THE REQUIREMENTS OF 37 CFR 1.61(A). THIS ALTERNATIVE PERMITS THE COMPLETION OF THE FILING REQUIREMENTS WITHIN ANY TERM SET BY THE PTO UNDER 37 CFR 1.53(D) TO WHICH THE EXTENSION PROVISIONS OF 37 CFR 1.136(A) APPLY. (WHEREAS, IF THE FILING IS AS AN INTERNATIONAL APPLICATION ENTERING THE U.S. STAGE THEN THE FEE, DECLARATION AND/OR ENGLISH TRANSLATION (WHERE NECESSARY) IS DUE WITHIN 20 MONTHS OF THE PRIORITY DATE BUT CAN BE PAID WITHIN 22 MONTHS OF THE PRIORITY DATE (OR IS DUE WITHIN 30 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 32 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 32 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 32 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 32 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 32 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 32 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 32 MONTHS OF THE PRIORITY DATE BUT CAN BE SUBMITTED WITHIN 37 CFR 1.495(C); HOWEVER, THE PROVISIONS OF 37 CFR 1.136 DO NOT APPLY TO THIS 22 OR (32 MONTH) PERIOD. 37 CFR 1.61(B).)

NOTE: THE DEADLINE FOR EXTERING THE NATIONAL PHASE IN THE U.S. FOR AN INTERNATIONAL APPLICATION WAS CLARIFIED IN THE NOTICE OF APRIL 28, 1987 (1079 O.G. 32 TO 46) AS FOLLOWS:

"The Patent and Trademark Office considers the International application to be pending until the 22nd month from the priority date if the United States has been designated and no Demand for International Preliminary Examination has been filed prior to the expiration of the 19th month from the priority date and until the 32nd month from the priority date if a Demand for International Preliminary Examination which elected the United States of America has been filed prior to the expiration of the 19th month from the priority date, provided that a copy of the international application has been communicated to the Patent nd Trademark Office within the 20 or 30 month period respectively. If a copy of the international application has not been communicated to the Patent and Trademark Office within the 20 or 30 month period respectively, the international application becomes abandoned as to the United States 20 or 30 months from the priority date respectivley. These periods have been placed in the rules as paragraph (h) of S 1.494 and paragraph (i) of S 1.495. A continuing application under 35 U.S.C. 365(c) and 120 may be filed anytime during the pendency of the international application."

# 18. Relate Back-35 U.S.C. 119 Priority Claim for Prior Application

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17, in turn itself claim(s) foreign priority (ies) as follows:

|        |           |  | countr   | у  | ар   | ppl. no.   | filed  | on   |  |
|--------|-----------|--|--|--|--|--|--|--|--|
|        | Th        | e ce   | rtified o  | opy (ies   | s) has (have   | e)   |  |  |  |
|        | []        |  |  |  |  | in pri   | or application 0   | /  | which was filed  |
|        | [         |  | is (are  | ) attach   | ed   |  |  |  |  |
| WARNII | NG:       | PTC<br>COL<br>PLA<br>ENT<br>SUC<br>COL<br>DOC<br>RES<br>NO<br>COL<br>INT | D BY THE PY OF TO RTIFIED OF ACED IN A TERED. S CH CERT NTINUING CUMENT SOURCES TATIONS NTINUING ERNATIO | INTERNA<br>HE PRIO,<br>COPY OF<br>A FOLDEI<br>SUCH FOL<br>GE APPLIC<br>SE FROM<br>SE REQUIF<br>TRANSF<br>GAPPLICA<br>WAL APP | ATIONAL BURE<br>RITY APPLICA<br>THE PRIORIT<br>R AND IS NOT<br>DERS ARE DO<br>DPIES MAY NO<br>CATION. AN A<br>THE FOLDER<br>RED TO REQUE<br>FER THE CERT<br>ATION ARE SU | EAU MAY NOT<br>ATION IN THE<br>Y APPLICATION<br>ASSIGNED A<br>ISPOSED OF<br>IOT BE AVAIVE<br>ALTERNATIVE<br>ALTERNATIVE<br>IEST TRANSF<br>TIFIED COPIES<br>BSTANTIAL. A<br>HICH HAVE N | BE RELIED ON WI<br>CONTINUING API<br>ON COMMUNICATE<br>LUS. SERIAL NUM<br>IF THE NATIONAL<br>LABLE IF NEEDED<br>WOULD BE TO<br>WOULD BE TO<br>WSFER THEM TO<br>ER, RETRIEVE THE<br>S, ENTER AND MAI<br>CCORDINGLY, THE<br>OT ENTERED THE | THOUT ANY PLICATION. ED BY THE BER UNLES STAGE IS N LATER IN PHYSICALL THE CONT E FOLDERS KE A RECOI | EN COMMUNICATED TO THE INTERNATIONAL BY NEED TO FILE A CERTIFIED THIS IS SO BECAUSE THE INTERNATIONAL BY THE NATIONAL STAGE IS SO THE PROSECUTION OF A LY REMOVE THE PRIORITY TINUING APPLICATION. THE SO MAKE SUITABLE RECORD THE OCCUMENTS IN FOLDERS OF STAGE MAY NOT BE RELIED |
| 19.    | Ma        | inte   | nance  | of Cop   | endency of   | f Prior App  | lication   |  |  |
| NOTE:  | FOI       | RE   | SPONSE   | IS FILED I   | IF A COPY OF<br>WITH THE PAF<br>1985 (1060 0.0   | PERS CONSTI  | N FILED IN THE PRIC<br>TUTING THE FILING   | OR APPLICA<br>G OF THE CO  | TION EXTENDING THE TERM<br>DNTINUATION APPLICATION.  |
|        | A.        |  | []   | Exten  | sion of time   | e in prior a   | pplication   |  |  |
|        | (Th<br>AP | is i<br>PLI  | tem MU<br>CATION   | JST BE   | COMPLE<br>E PERIOD S   | TED AND<br>SET IN THE  | THE PAPERS<br>PRIOR APPLI  | FILED I  | N THE PRIOR<br>HAS RUN)  |
|        |           |  |  | []   |  | , fee and r  | esponse exten  | ds the te  | rm in the pending prior  |
|        |           |  |  | [ ]  | A copy of  | the petition   | filed in prior ap  | nlication is   | s attached   |

|       | В.  | []  | Cond   | itional Petition for Extension of Time In Prior Application   |
|-------|---|---|--|---|
|       |   |   | (con   | nplete this item if previous item not applicable)   |
|       |   |   | []   | A conditional petition for extension of time is being filed in the pending prior application.   |
|       |   |   | []   | A copy of the conditional petition filed in the prior application is attached   |
| 20.   | Furth   | er Invei  | ntorshi  | p Statement Where Benefit of Prior Application(s) Claimed   |
| NOTE: | INVEN<br>FILED<br>THE IN                          | TORS NAM<br>REQUEST<br>VENTION                            | MED IN TI<br>ING DELE<br>BEING CL                                  | ONTINUATION-IN-PART, OR DIVISIONAL APPLICATION IS FILED BY LESS THAN ALL THE HE PRIOR APPLICATION A STATEMENT MUST ACCOMPANY THE APPLICATION WHEN ETION OF THE NAMES OF THE PERSON OR PERSONS WHO ARE NOT INVENTORS OF AIMED IN THE CONTINUATION, CONTINUATION-IN-PART, OR DIVISIONAL APPLICATION. S ADDED]. (DEALING WITH THE FILE WRAPPER CONTINUATION SITUATION).  |
| NOTE: | BY AM<br>WHER<br>ADDIT<br>APPLIO<br>NO AD<br>SAME | ENDMENT<br>E A NEW C<br>IONAL INV<br>CATION W<br>DITIONAL | T, AN OAT<br>DATH OR S<br>ENTORS<br>HICH DIS<br>OATH OR<br>THAN AL | NUATION-IN-PART APPLICATION WHICH ADDS AND CLAIMS ADDITIONAL DISCLOSURE IT OR DECLARATION AS REQUIRED BY S 1.63 MUST BE FILED. IN THOSE SITUATIONS DECLARATION IS REQUIRED DUE TO ADDITIONAL SUBJECT MATTER BEING CLAIMED, MAY BE NAMED IN THE CONTINUING APPLICATION. IN A CONTINUATION OR DIVISIONAL CLOSES AND CLAIMS ONLY SUBJECT MATTER DISCLOSED IN A PRIOR APPLICATION, IN DECLARATION IS REQUIRED AND THE APPLICATION MUST NAME AS INVENTORS THE LATHE INVENTORS IN THE PRIOR APPLICATION. 37 CFR 1.60(C). (DEALING WITH THE ON). |
|       |   |   | (com   | nplete applicable item (a), (b) and/or (c) below)   |
|       | (a)   | [x]   | applic   | application discloses and claims only subject matter disclosed in the prior cation whose particulars are set out above and the inventor(s) in this cation are   |
|       |   |   | []   | the same.   |
|       |   |   | [x]  | the following inventor(s) have been deleted:  Jay Qin, Robin Bek  |
|       |   |   |  | (type name(s) of inventor(s) to be deleted)   |
|       |   |   | [x]  | the following inventor(s) have been added: <u>David Utley, Stuart D. Edwards</u>  |
|       |   |   |  | (type name(s) of inventor(s) to be added)   |
|       | (b)   | [ ]   | declar   | application discloses and claims additional disclosure and a new ration or oath is being filed. With respect to the prior application the for(s) in this application are  |
|       |   |   | []   | the same.   |
|       |   |   | [ ]  | the following inventor(s) have been deleted:  |
|       |   |   |  | (type name(s) of inventor(s) to be deleted)   |
|       |   |   | [ ]  | the following inventor(s) have been added:  |
|       |   |   |  | (type name(s) of inventor(s) to be added)   |

|        | (c)  | (c) The inventorship for all the claims in this application are   |  |  |  |  |  |
|--------|--|---|--|--|--|--|--|
|        | (0)  |   |  |  |  |  |  |
|        |  | [x]   | the same.  |  |  |  |  |
|        |  | []  | not the same, and an explanation, including the ownership of the various claims at the time the last claimed invention was made [ ] is submitted. [ ] will be submitted.   |  |  |  |  |
| 21.    | Aban   | donmei  | nt of Prior Application (if applicable)  |  |  |  |  |
|        | []   | when<br>when  | e abandon the prior application at a time while the prior application is pending or<br>the petition for extension of time or to revive in that application is granted and<br>this application is granted a filing date so as to make this application copending<br>aid prior application.  |  |  |  |  |
| NOTE:  | CONTII<br>OF TIM<br>APPLIC   | CORDING TO THE NOTICE OF MAY 13, 1983 (103, TMOG 6-7) THE FILING OF A CONTINUATION OR ONTINUATION-IN-PART APPLICATION IS A PROPER RESPONSE WITH RESPECT TO A PETITION FOR EXTENSION OF TIME OR A PETITION TO REVIVE AND SHOULD INCLUDE THE EXPRESS ABANDONMENT OF THE PRIOR OPPLICATION CONDITIONED UPON THE GRANTING OF THE PETITION AND THE GRANTING OF A FILING DATE TO BE CONTINUING APPLICATION. |  |  |  |  |  |
| 22.    | Petitio  | on for S  | Suspension of Prosecution for the Time Necessary to File an Amendment  |  |  |  |  |
| WARNII | SITI<br>AN I<br>INV<br>REJ   | UATIONS<br>EARLIER /<br>ENTION (<br>IECTED O  | OF A NEW APPLICATION MAY BE FINALLY REJECTED IN THE FIRST OFFICE ACTION IN THOSE WHERE (1) THE NEW APPLICATION IS A CONTINUING APPLICATION OF, OR A SUBSTITUTE FOR, APPLICATION, AND (2) ALL THE CLAIMS OF THE NEW APPLICATION (A) ARE DRAWN TO THE SAME CLAIMED IN THE EARLIER APPLICATION, AND (B) WOULD HAVE BEEN PROPERLY FINALLY N THE GROUNDS OF ART OF RECORD IN THE NEXT OFFICE ACTION IF THEY HAD BEEN ENTERED IER APPLICATION." MPEP, S 706.07(B). |  |  |  |  |
| NOTE:  | WHERE IT IS POSSIBLE THAT THE CLAIMS ON FILE WILL GIVE RISE TO A FIRST ACTION FINAL FOR THIS CONTINUATION APPLICATION AND FOR SOME REASON AN AMENDMENT CANNOT BE FILED PROMPTLY (E.G., EXPERIMENTAL DATA IS BEING GATHERED) IT MAY BE DESIRABLE TO FILE A PETITION FOR SUSPENSION OF PROSECUTION FOR THE TIME NECESSARY. |   |  |  |  |  |  |
|        |  |   | (check the next item, if applicable)   |  |  |  |  |
|        | []   | There<br>to File  | is provided herewith a Petition To Suspend Prosecution for the Time Necessary An Amendment (New Application Filed Concurrently)  |  |  |  |  |